UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION THIS DOCUMENT RELATES TO: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 18-op-45090[1]	MDL No. 2804 Case No. 1:17-md-2804 Judge Dan Aaron Polster

AMENDMENT BY INTERLINEATION

Plaintiff County of Summit, Ohio (the "County" or "Plaintiff"), respectfully submits the following Amendment by Interlineation to the Third Amended Complaint (Dkt. No 1465). This Amendment by Interlineation includes dispensing-related claims against the CVS, Walgreens, Rite Aid, Walmart, and HBC/Giant Eagle Entities, described further below, who collectively purchased approximately ***178 million*** estimated 10mg equivalent pills[2] in the County from 2006 to 2014, the years for which ARCOS data is available.[3] Over the same time period, individually, CVS

[1] Purdue Pharma L.P. and its related corporate entities (Purdue Pharma, Inc. and The Purdue Frederick Company, Inc.) have been severed from this action and are not part of this Amendment by Interlineation ("Amendment"). The County has used the existing caption only for ease of reference. None of the allegations in this Amendment are asserted against Purdue, which will not be served with this Amendment. Similarly, Insys Therapeutics, Inc. has been severed due to a bankruptcy stay and will not be served, and a number of defendants have been dismissed. This Amendment does not seek to pursue claims against any of these severed or dismissed parties, but only to add dispensing-related claims against certain pharmacy entities.

[2] For ease of comparing different opioid strengths, other dosages are converted into 10 mg pills.

[3] The opioid purchases disclosed in the ARCOS data serve as an effective proxy for the opioids dispensed by the retail pharmacies, which have no incentive to purchase drugs they do not plan to sell.

purchased more than ***62 million***, Walgreens more than ***52 million***, Rite Aid more than ***35 million***, Walmart nearly ***4 million***, and Giant Eagle more than ***25 million*** estimated 10mg equivalent pills in Summit County.

The County amends the "PARTIES" allegations of Section II.B.4 to include as follows:

1. CVS Entities

1. Defendant CVS Indiana L.L.C., is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. Defendant CVS Rx Services, Inc. is a New York corporation with its principal place of business in Woonsocket, RI. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a wholly owned subsidiary of CVS Health Corporation. Defendant CVS Pharmacy, Inc. is both a DEA registered "distributor"[4] and a DEA registered "dispenser"[5] of prescription opioids and is registered to do business in Ohio. Defendant Ohio CVS Stores, LLC is an Ohio corporation with its principal place of business in Rhode Island, and is registered to do business in Ohio.

2. Defendants CVS Indiana L.L.C., CVS Rx Services, Inc., CVS Pharmacy, Inc., and Ohio CVS Stores, LLC are collectively referred to as "CVS." CVS, conducts business as a licensed wholesale distributor and dispenser. At all times relevant to this Complaint, CVS distributed and/or dispensed prescription opioids throughout the United States, including in Ohio and Summit County~~Plaintiffs' communities~~ specifically. CVS expanded its pharmacy operations in 2019 with the acquisition of the Ritzman Pharmacy chain. CVS is liable as successor for the Ritzman pharmacy operations.

The County amends the "PARTIES" allegations of Section II.B.6 as follows:

[4] 21 U.S.C. §802(11) and §822(a)(1).
[5] 21 U.S.C. §802(10) and §822(a)(2).

6. HBC and Giant Eagle Entities

3. Defendant HBC Service Company ("HBC") is an operating division of Defendant Giant Eagle, Inc. ("Giant Eagle"). HBC operated as a licensed wholesale distributor wholesaler in Ohio, licensed by the State of Ohio Board of Pharmacy. Giant Eagle is a Pennsylvania corporation with its principal place of business in Washington, Pennsylvania. At all times relevant to this Complaint, HBC distributed and Giant Eagle dispensed prescription opioids in Ohio and Summit County specifically.

The County amends the "PARTIES" allegations of Sections II.B.11-13 as follows:

11. Rite Aid Entities.

4. Defendant Rite Aid Corporation is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. Defendant Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. is a subsidiary of Rite Aid Corporation and is itself Maryland corporation with its principal office located in Camp Hill, Pennsylvania. At all times relevant to this Complaint, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. distributed prescription opioids throughout the United States, including in Ohio and Summit County specifically. Defendant Rite Aid Headquarters Corporation is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. Rite Aid Headquarters Corp., by and through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and pharmacy operator.

5. During the relevant time period, and as further alleged below, Rite Aid entities also owned and operated pharmacies in the County through Defendant Rite Aid of Ohio, Inc. Defendant Rite Aid of Ohio, Inc. is an Ohio corporation with its principal place of business in Ohio. Rite Aid of Ohio, Inc. was in the business of holding and operating retail pharmacies in Ohio, including in Summit County, on behalf of its parent company Rite Aid Corporation. Rite

Aid of Ohio, Inc. orders of controlled substances from Rite Aid of Maryland, Eckerd Corporation — another Rite Aid subsidiary, and other wholesalers. These controlled substances are distributed and dispensed according to practices and procedures established by Rite Aid Corporation and Rite Aid Headquarters Corporation. Defendants Rite Aid Corporation, Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc., and Rite Aid of Ohio, Inc. are collectively referred to as "Rite Aid."

6. Rite Aid Corporation established national policies and procedures governing the dispensing of controlled substances throughout the United States that it directed and intended that those policies and procedures would be implemented by its subsidiaries on a nationwide basis including, specifically, in Ohio and Summit County. At all times relevant to this Complaint, Defendant Rite Aid Corporation was responsible for directing and implementing policies and procedures governing the dispensing of controlled substances by its subsidiaries, including but not limited to Rite Aid of Ohio, Inc., throughout the United States, including in Ohio and the County specifically.

12. Walgreens Entities

7. Defendant Walgreen Co. is an Illinois corporation with its principal place of business in Deerfield, Illinois. Defendant Walgreen Eastern Co., Inc. is a New York corporation with its principal place of business in Deerfield, Illinois. Defendants Walgreen Co. and Walgreen Eastern Co. are collectively referred to as "Walgreens." Walgreens conducts business as a licensed wholesale distributor.–During the relevant time period, and as further alleged below, Walgreens entities also owned and operated pharmacies in the County. At all times relevant to this Complaint, Walgreens distributed and dispensed prescription opioids throughout the United States, including in Ohio and Summit County~~Plaintiffs' communities~~ specifically.

8. Expanding its dispensing operations, Walgreens also acquired a number of former Rite-Aid stores, including in the County. Walgreens is liable as a successor for these stores' prior conduct, as well as for its own operations.

13. Walmart Entities

9. Defendant Walmart Inc., formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in ~~Bentonville,~~ Arkansas. Walmart, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor and as a dispenser. Defendant Wal-Mart Stores East, Inc. is a Delaware corporation with its principle place of business in Arkansas. Defendants Walmart Inc. and Wal-Mart Stores East, Inc. are collectively referred to as "Walmart." At all times relevant to this Complaint, Walmart distributed and dispensed prescription opioids throughout the United States, including in Ohio and Summit County~~Plaintiffs' communities~~ specifically.

10. Collectively, Defendants CVS, Rite Aid, Walgreens, Walmart, and Giant Eagle are referred to as "National Retail Pharmacies." Defendants AmerisourceBergen, Anda, Cardinal, Discount Drug, HBC, Henry Schein, McKesson, Miami-Luken, Prescription Supply, and the National Retail Pharmacies are collectively referred to as the "Distributor Defendants."

The County Amends the "Factual Allegations" by inserting the following immediately after paragraph 627 and immediately before the heading to Section I.E.3.4.b (titled Multiple Enforcement Actions against the National Retail Pharmacies Confirm[] their Compliance Failures) therein:

A. The National Retail Pharmacies' Obligations Are Responsible for Guarding Against Diversion from Their Retail Stores.

1. The National Retail Pharmacies have common-law and statutory duties to guard against, and not fuel, diversion. In addition to their responsibilities as distributors, as dispensers,

they must maintain effective systems to guard against diversion at the pharmacy level. Under the common law, the National Retail Pharmacies had a duty to exercise reasonable care in delivering dangerous narcotic substances. Defendants breached their duty to exercise reasonable care in delivering narcotic substances and both created and failed to prevent a foreseeable risk of harm to Summit County. As the supply of opioids and the evidence of addiction to and abuse of these drugs grew, these Defendants were again reminded of both the nature and harms of opioid exposure and use.

2. Each Defendant assumed a duty, when speaking publicly about opioids and their efforts and commitment regarding diversion of prescription opioids, to speak accurately and truthfully.

3. Under the federal Controlled Substances Act ("CSA") and Ohio controlled-substances laws, they likewise were required to design and operate effective systems to guard against diversion. *See, e.g.*, 21 U.S.C. § 823. Federal regulations issued under the CSA also mandate that all registrants "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Defendants also have independent duties under Ohio law. The Ohio Administrative Code imposes obligations and duties upon "licensees" and "registrants," to "provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs." O.A.C. § 4729-9-05(A). These duties extend to manufacturers, wholesalers, and pharmacies alike.

4. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states,

"[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Pharmacists must ensure that prescriptions of controlled substances are "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a); *see also* O.A.C. §§ 4729-5-21(A) & 4729-5-30(A). The DEA has recognized that "as dispensers of controlled substances, pharmacists and pharmacy employees are often the last line of defense in preventing diversion."[6]

5. Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist.

6. Although it acts through its agents, the pharmacy, as the DEA registrant, is ultimately responsible to prevent diversion, as described above.[7] To that end, the Tenth Appellate District of the Court of Appeals of Ohio has determined that the Ohio Administrative Code "places the ultimate responsibility upon the 'registrant' … to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs."[8]

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[6] 2012 Dear Registrant letter to pharmacy registrants, http://ppsconline.com/articles/2012/FL_PDAC.pdf; also available at Anda_Opioids_MDL_0000137151 (news release).

[7] *The Medicine Shoppe; Decision and Order*, 79 FR 59504, 59515 (DEA Oct. 2, 2014) (emphasis added); *see also Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195*; Decision and Order, 77 FR 62316-01 ("When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the entity, not the pharmacist, can be charged with the requisite knowledge."); *Top RX Pharmacy*; Decision and Order, 78 FR 26069, 62341 (DEA Oct. 12, 2012) (same); *cf. Jones Total Health Care Pharmacy LLC and SND Health Care LLC v. Drug Enforcement Administration*, 881 F.3d 82 (11th Cir. 2018) (revoking pharmacy registration for, *inter alia*, dispensing prescriptions that prescriptions presented various red flags, i.e., indicia that the prescriptions were not issued for a legitimate medical purpose without resolving red flags).

[8] *Linden Med. Pharm. v. Ohio State Bd. of Pharm.*, 2001 Ohio App. LEXIS 2041, at *24 (Ohio Ct. App. 11th Dist. May 8, 2001) (explaining that licensees electing to operate a business through employees are responsible to the licensing authority for their conduct").

7. Thus, in addition to their duties as distributors, the National Retail Pharmacies also had a duty to design and implement systems to prevent diversion of controlled substances in their retail pharmacy operations. The National Retail Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

B. The National Retail Pharmacies Understood Both the Existence and the Importance of their Obligations to Guard Against Diversion at the Pharmacy Level.

8. The National Retail Pharmacies were well aware of these obligations. DEA has repeatedly emphasized that retail pharmacies, including the National Retail Pharmacies, are required to implement systems that detect and prevent diversion and must monitor for and report red flags of diversion. When red flags appear, the pharmacy's "corresponding responsibility" under 21 C.F.R. § 1306.04(a) requires it either to take steps (and document those steps) to resolve the issues or else to refuse to fill prescriptions with unresolvable red flags.[9]

9. Not only do National Retail Pharmacies often have firsthand knowledge of dispensing red flags – such as distant geographic location of doctors from the pharmacy or customer, lines of seemingly healthy patients, out-of-state license plates, and cash transactions, and other significant information – but they also have the ability to analyze data relating to drug utilization and prescribing patterns across multiple retail stores. As with the other Distributor Defendants and Marketing Defendants, these data points give the National Retail Pharmacies insight into prescribing and dispensing conduct that enables them to play a valuable role in the preventing diversion and fulfilling their obligations under the CSA.

[9] *Pharmacy Doctors Enterprises, Inc. v. Drug Enf't Admin.*, No. 18-11168, 2019 WL 4565481, at *5 (11th Cir. Sept. 20, 2019).

10. The DEA has also repeatedly affirmed the obligations of National Retail Pharmacies to maintain effective controls against diversion in regulatory action after regulatory action.[10] In addition, the DEA, among others, has provided extensive guidance to National Retail Pharmacies concerning their duties to the public. In particular, the guidance advises how to identify red flags and other evidence of diversion.

11. For example, DEA guidance instructs pharmacies to monitor for red flags that include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances as compared to other practitioners in the area, and (2) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Most of the time, these attributes are not difficult to detect and should be easily recognizable by the National Retail Pharmacies' diversion control systems.

12. Other signs of diversion can be observed through data available to the National Retail Pharmacies. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in illegitimate prescribing.

13. The DEA has also conducted meetings with retail pharmacies, including the National Retail Pharmacies. For example, in December 2010, DEA hosted a meeting with CVS's representatives and counsel and advised CVS of the "red flags . . . that a pharmacy should be

[10] *See, e.g.*, Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; 77 Fed. Reg. 62,316 (DEA Oct. 12, 2012) (decision and order); East Main Street Pharmacy, 75 Fed. Reg. 66,149 (DEAOct. 27, 2010) (affirmance of suspension order); Holiday CVS, L.L.C. v. Holder, 839 F.Supp.2d 145 (D.D.C. 2012); Townwood Pharmacy; 63 Fed. Reg. 8,477 (DEA Feb. 19, 1998) (revocation of registration); Grider Drug 1 & Grider Drug 2; 77 Fed. Reg. 44,069 (DEA July 26, 2012) (decision and order); The Medicine Dropper; 76 Fed. Reg. 20,039 (DEA April 11, 2011) (revocation of registration); Medicine Shoppe-Jonesborough; 73 Fed. Reg. 363 (DEA Jan. 2, 2008) (revocation of registration).

familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose."[11]

14. Examples of red flags that the DEA identified during its meeting with CVS include:

a. many customers receiving the same combination of prescriptions (*i.e.*, oxycodone and alprazolam);

b. many customers receiving the same strength of controlled substances (*i.e.*, 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam);

c. many customers paying cash for their prescriptions;

d. many customers with the same diagnosis codes written on their prescriptions (*i.e.*, back pain, lower lumbar, neck pain, or knee pain);

e. individuals driving long distances to visit physicians and/or to fill prescriptions.[12]

15. As another example, in a 2016 presentation to the American Pharmacists Association, the DEA reiterated that retail pharmacies must watch for red flags such as: large numbers of customers who: receive the same combination of prescriptions, receive the same strength of controlled substance prescription (often for the strongest dose), have prescriptions from the same prescriber, and have the same diagnosis code.[13]

16. In 2006, the National Association of Chain Drug Stores ("NACDS") issued a "Model Compliance Manual" intended to "assist NACDS members" in developing their own compliance programs.[14] The Model Compliance Manual notes that a Retail Pharmacy may:

> Generate and review reports for its own purposes" and refers to the assessment tools identified by CMS in its Prescription Drug Benefit Manual chapter on fraud, waste and abuse, including:

[11] Declaration of Joe Rannazzisi in Holiday CVS, L.L.C. v. Holder, 839 F. Supp.2d 145 (D.D.C. 2012).
[12] *Id.*
[13] CAH_MDL2804_00041751
[14] CAH_MDL2804_00842870

- Drug Utilization Reports, which identify the number of prescriptions filled for a particular customer and, in particular, numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by a customer. A customer with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports, and the customer and his or her prescribing providers can be contacted and explanations for use can be received.

  Prescribing Patterns by Physician Reports, which identify the number of prescriptions written by a particular provider and focus on a class or particular type of drug such as narcotics. These reports can be generated to identify possible prescriber or other fraud.

- Geographic Zip Reports, which identify possible "doctor shopping" schemes or "script mills" by comparing the geographic location (zip code) of the patient to the location of the provider who wrote the prescription and should include the location of the dispensing pharmacy.

17. According to law and industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

18. The National Retail Pharmacies also have particularly detailed information that would have put them on notice of, and could have been used to prevent, diversion. At the pharmacy level, the National Retail Pharmacies would have been able to observe customers, including, for example, customers with insurance coverage making cash payments. They could also identify customers filling prescriptions at multiple pharmacy branches or from different doctors, or patterns of unusual or suspicious prescribing from a particular medical provider. Indeed, CVS Health president and CEO Larry Merlo has described the company as “America’s front door to health care with a presence in nearly 10,000 communities across the country,” and this position as allowing it to “see firsthand the impact of the alarming and rapidly growing epidemic of opioid addiction and misuse.”

19. As explained above, in addition to their duties as distributors, the National Retail Pharmacies also had a duty to design and implement systems to prevent diversion of controlled

substances in their retail pharmacy operations. Specifically, the National Retail Pharmacies had a duty to analyze data and the personal observations of their employees for known red flags such as (a) multiple prescriptions to the same patient using the same doctor; (b) multiple prescriptions by the same patient using different doctors; (c) prescriptions of unusual size and frequency for the same patient; (d) orders from out-of-state patients or prescribers; (e) an unusual or disproportionate number of prescriptions paid for in cash; (f) prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose. The National Retail Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

20. As described above and further below, the National Retail Pharmacies also possessed sufficiently detailed and valuable information that other companies were willing to pay them for it. As both national pharmacy chains and distributors, the Chain Pharmacies have especially deep knowledge of their retail stores' orders, prescriptions, and customers. This is underscored by the fact that Walgreens is able to sell the contents of its patients' prescriptions to data-mining companies such as IMS Health, Inc. In 2010, for example, Walgreen's fiscal year 2010 SEC Form 10-K disclosed that it recognizes "purchased prescription files" as "intangible assets" valued at $749,000,000. Walgreens could, and did, use "[d]ata mining . . . [a]cross Walgreens retail pharmacies to determine the maximum amount that a pharmacy should be allowed to receive . . . ." in setting ceilings for its stores.[15] More recently, as part of an agreement with AmerisourceBergen, Walgreens gained even more insight, as Walgreens has the ability to

[15] WAGMDL00757776.

nominate up to two members of the Board of Directors of AmerisourceBergen. Currently, Walgreen's Co-Chief Operating Officer, who oversees Walgreens' business operation, including distribution, sits on the AmerisourceBergen Board of Directors.

21. Similarly, CVS Caremark's Director of Managed Care Operations, Scott Tierney, testified that CVS's data vendors included IMS Health, Verispan, and Walters Kluwers and that CVS used the vendors for "analysis and aggregation of data" and "some consulting services." He also testified that CVS would provide the vendors with "prescriber level data, drug level data, plan level data, [and] de-identified patient data."[16]

22. Each of the National Retail Pharmacies had complete access to all prescription opioid dispensing data related to its pharmacies in the County, complete access to information revealing the doctors who prescribed the opioids dispensed in its pharmacies in and around the County, and complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around the County. Each of the National Retail Pharmacies likewise had complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies in and around the County, complete access to information revealing the opioids prescriptions dispensed by its pharmacies in and around the County, and complete access to information revealing the opioids prescriptions dispensed by its pharmacies in and around the County. Further, each of the National Retail Pharmacies had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by its pharmacies in and around the County and

[16] Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134 (U.S.) *245-46 (Feb. 22, 2011).

complete access to information revealing the size and frequency of prescriptions written by specific doctors across its pharmacies in and around the County.

23. As described further below, the National Retail Pharmacies failed to fulfill their legal duties and instead, routinely dispensed controlled substances while ignoring red flags of diversion and abuse. The unlawful conduct by these Defendants is a substantial cause for the volume of prescription opioids and the public nuisance plaguing Summit County.

i. CVS

1. CVS Failed to Implement Effective Policies and Procedures to Guard Against Diversion from its Retail Stores.

24. By 2009, CVS Pharmacy, Inc. owned and/or operated more than 9,000 pharmacies in the United States. According to its website, CVS now has more than 9,900 retail locations. At all times relevant herein, CVS pharmacies sold controlled substances, including FDA Schedule II and FDA Schedule III controlled substances otherwise known as opiate narcotics or opioids.

25. Until October 6, 2014, CVS pharmacies ordered and were supplied FDA Schedule III hydrocodone combination products (HCPs) from a combination of outside vendors and CVS distribution centers. CVS pharmacies also received Schedule II opioids from outside vendors, including Cardinal and McKesson.

26. CVS Pharmacy, Inc. instituted, set-up, ran, directed and staffed with its own employees the majority of the SOM functions for its dispensing arms.

27. CVS also lacked meaningful policies and procedures to guide its pharmacy staff in maintaining effective controls against diversion, even as they evolved over time. Not until 2012 did CVS create guidelines explaining in more detail the "red flags" or cautionary signals that CVS pharmacists should be on the lookout for to prevent diversion and to uphold their corresponding

responsibilities to ensure that all dispensed controlled substances are issued for a legitimate medical purpose.[17]

28. Even so, CVS's conduct, and the volume it dispensed in the County thereafter indicates that its policies were not applied. Further, as discussed elsewhere in the Third Amended Complaint, CVS had performance metrics in place that pressured pharmacists to put profits ahead of safety. Concerning the metrics at CVS, one pharmacist commented that, "You get stressed, and it takes your mind away from the actual prescriptions." Another former CVS pharmacist recalled that "[e]very prescription [wa]s timed," and a backlog would pop up in color on pharmacists computer screens if they fell behind.[18] Additionally, CVS has faced discrimination complaints alleging that the company's "Metrics" system set unobtainable goals — or at least, goals that could not be obtained without violating the laws and practice rules governing pharmacists' professional responsibilities, edging out older pharmacists.

29. A nationally-known expert and teacher of pharmacology commented in the media that the pace and pressure of prescription quotas appeared to be having an impact on accuracy. He described data from the FDA's Adverse Event Reporting System as showing a 450% increase in reported medication errors since 2010. Anecdotally, he also "heard some pharmacists say, 'It's a blur as to what happened during the day and I can only pray I didn't make any serious mistakes.'"[19]

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[17] Guidelines for Dispensing Controlled Substances, Document ID ROPP-0061, January 4, 2012, CVS-MDLT1-000055548 – 55550.

[18] Sam Roe, Ray Long, and Karisa King, Contract Reporters, *Pharmacies Miss Half of Dangerous Drug Combinations*, Dec. 15, 2016, http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html

[19] ReachMd, *Are Business Tactics at Some Pharmacies Risking Your Health?* (Nov. 8, 2017), https://reachmd.com/news/are-business-tactics-at-some-pharmacies-risking-your-health/1610793/

30. This pressure and focus on profits would not only lead to mistakes, it also would necessarily deter pharmacists from carrying out their obligations to report and decline to fill suspicious prescriptions and to exercise due care in ascertaining whether a prescription is legitimate. Indeed, "a survey by the Institute for Safe Medication Practices (ISMP) revealed that 83% of the pharmacists surveyed believed that distractions due to performance metrics or measured wait times contributed to dispensing errors, as well as that 49% felt specific time measurements were a significant contributing factor."[20] In 2013, the National Association of Boards of Pharmacy (NABP), passed a resolution which cited this survey and additionally stated that "performance metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment" and "the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy."[21]

2. CVS Failed to Maintain Effective Controls Against Diversion from its Summit County Pharmacies.

[20] NAPB, Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13) (June 5, 2013), https://nabp.pharmacy/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13/

[21] *Id.*

31. Through 20 pharmacies in Summit County, CVS purchased more than ***62 million*** estimated 10mg equivalent pills in Summit County from 2006 to 2014, the years for which ARCOS data is available. Over the same time frame, CVS was responsible for 16% of the 10mg equivalent pills purchased in the County.

32. As a vertically integrated distributor and dispenser of prescription opioids, CVS knew or should have known that an excessive volume of pills was being sold into Summit County.

33. The sheer volume of prescription opioids distributed to and dispensed by CVS pharmacies in and around Summit County is indicative of potential diversion and required appropriate due diligence.

34. Further, analysis of ARCOS data also reveals that, every year between 2006 and 2014, three separate CVS locations in the County purchased opioid volumes, measured in both dosage unit and morphine milligram equivalent ("MME") in the 90th percentile among retail and chain pharmacies for a given year.

35. Discovery will reveal that CVS knew or should have known that its pharmacies in Ohio, and the surrounding area, including West Virginia, Michigan, and Kentucky, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines,

or prescription "cocktails";[22] (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. The National Retail Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

36. Failures regarding dispensing in CVS's Florida stores also allowed diverted opioids to be funneled into Summit County. The well-travelled path between Florida and Ohio is described in the Third Amended Complaint, and further with respect to pharmacy stores below.

37. CVS also saw huge increases in the quantity of oxycodone it dispensed in Florida from 2006 to 2010. For example, starting with an already high baseline, a single CVS ordered approximately four times the amount of oxycodone a typical pharmacy orders in one year in 2006. By 2010, the same pharmacy's 10-month history showed quantities more than thirty times the amount of oxycodone a typical pharmacy orders in one year, and the pharmacy's supervisor could not explain why the volume was so high. During that time, Cardinal was the pharmacy's main distributor, and two of CVS's Florida pharmacies were among Cardinal's top four retail pharmacy customers, dispensing a staggering amount of oxycodone compared to Cardinal's other Florida

[22] According to definitions applied by CVS for suspicious order monitoring purposes, "cocktails for opioids are methadone, muscle relaxants, stimulants and benzodiazepines." CVS-MDLT1-00000412.

customers. Interviews with employees of these pharmacies revealed that they routinely observed red flags and obvious signs that they were filling illegitimate prescriptions. One set a daily limit of oxycodone 30mg prescriptions the pharmacy would fill each day, basing the limit on the amount in stock that day, so as to ensure that the "real pain patients" could get their prescriptions filled.[23] The pharmacy usually reached its limit by lunchtime each day, and at times within 30 minutes of opening. Customers, aware that prescriptions were first come, first served, would line up outside the store as early as 7:45 AM. An employee acting as "bouncer" included escorting off the premises customers who were "hooked" on opioids and became belligerent if their prescriptions were refused among his job duties.[24] Although CVS/Caremark, Inc. had in place dispensing guidelines for controlled substances prescriptions, these guidelines were not followed at these stores. Rather, they dispensed controlled substances prescriptions despite the existence of "warning signs" in the guidelines.[25]

38. Because of its vertically integrated structure, CVS has access to complete information regarding red flags of diversion across its pharmacies in and around Summit County, but CVS failed to utilize this information to effectively prevent diversion.

39. Indeed, as late as 2014, internal documents show that an Akron CVS received a failing grade — even by Cardinal's standards, from Cardinal's suspicious order monitoring program (although Cardinal did not report CVS's orders as suspicious that year). CVS never submitted a single suspicious order report from this location, which was the third largest purchaser of opioid dosage units in the County in 2013 and 2014.

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[23] Declaration of Joseph Rannazzisi, *Holiday CVS, LLC d/b/a CVS/Pharmacy Nos. 5195/219 v. Eric Holder, Jr. et al.*, No. 1:12-cv-191, Doc. 19-6 ¶¶ 38-41 (D.D.C. Feb. 24, 2012).
[24] *Id.* ¶ 41.d.
[25] *Id.* ¶¶ 48 & 56.

40. The pharmacy purchased over ***seven million*** dosage units of opioids in under a decade. From 2009 to 2011 alone, it purchased nearly one million dosage units per year.

The graph below shows a comparison between this Akron, Ohio CVS store and average pharmacy purchasing volumes, both in Ohio and nationally, from 2006 to 2014 based on the ARCOS data for that time:

41. CVS also should have been aware of other red flags at this Akron location. In 2008, a man overdosed on heroin in the CVS pharmacy parking lot. The next year, police arrested the occupant of a stolen car in the same parking lot, discovering a syringe and a metal spoon with OxyContin residue in the course of the arrest.

42. At another, Cuyahoga Falls CVS, one of CVS's pharmacists lost her license for misconduct involving opioids. The Ohio Board of Pharmacy issued the indefinite suspension in 2009.

43. As described above, in 2019, CVS acquired and is successor in interest to Ritzman Pharmacies, which includes Ritzman Pharmacy #101 in Akron. This pharmacy purchased (and by extension, dispensed) far more opioids relative to other pharmacies in the County, state, and nation. Each year for which ARCOS data is available, its purchasing volume was roughly three times the state and national averages for opioids. From 2015 to 2017, Cardinal ranked this pharmacy among the top 50 in the United States for oxycodone sales. The graph below highlights the pharmacy's opioid purchasing volume as compared to average pharmacies in Ohio and nationally, from 2006 to 2014.

44. Meanwhile, despite the conduct described above, CVS has attempted to portray itself as a good corporate citizen, not a cause of the opioid crisis. To that end, it claims to be "playing an active role in the search for solutions to the opioid crisis in a number of ways."

45. Confirming its systemic failures to implement and adhere to adequate controls against diversion, CVS has repeatedly faced enforcement actions. In addition to those listed in the

Third Amended Complaint, as recently as March 2019, CVS Pharmacy, Inc. (including all of its relevant subsidiaries and affiliates) entered into a $535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island, acting on behalf of the United States and the DEA's Providence Office. In connection with the settlement, a DEA agent stated: "Pharmacies put patients at risk when they dispense Schedule II narcotics, which have the highest potential for abuse, without a valid and legal prescription.[26]

46. In August of 2018, CVS paid $ 1 million to resolve allegations that CVS pharmacies throughout the Northern District of Alabama violated record-keeping requirements under the CSA and its implementing regulations, the largest civil fine paid in Alabama by a DEA registrant.

47. In June of 2018, CVS paid $1.5 million to resolve allegations that CVS pharmacies in Long Island, New York failed to timely report the loss or theft of controlled substances, including hydrocodone, recognized as one of the most commonly diverted controlled substances.

48. In 2013, CVS agree to pay $ 11 million to resolve allegations it violated the CSA and related federal regulations at its retail stores in Oklahoma and elsewhere by: (1) creating and using "dummy" DEA registration numbers on dispensing records, including records provided to state prescription drug monitoring programs; (2) filling prescriptions from prescribers who lacked current or valid DEA numbers; and (3) substituting the DEA number of non-prescribing practitioners for the DEA numbers of prescribers on prescription records.

ii. Walgreens

A. Walgreens Failed to Maintain and Apply Adequate Policies and Procedures, and Used Those It Did Develop for Show, Not Real and Lasting Change.

[26] https://www.dea.gov/press-releases/2019/04/16/cvs-pay-535000-filling-invalid-prescriptions

49. Although Walgreens purported to have in place "Good Faith Dispensing" ("GFD") Policies for many years, it failed to meaningful apply policies and procedures, or to train employees in its retail pharmacies, on identifying and reporting potential diversion.

50. In 2009, the DEA issued an Order to Show Cause regarding Walgreens's dispensing practices at a San Diego pharmacy. Although the Order addressed this specific location, the response, including Walgreens' internal assessment of its compliance, or lack thereof, revealed systemic failures from which its Summit County pharmacies would not have been exempt. Indeed, during the course of the investigation, Walgreens internally noted that it currently had "no training" internally for employees dispensing controlled substances.[27] Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement regarding all "Walgreens… pharmacy locations registered with the DEA to dispense controlled substances," requiring Walgreens to implement significant nationwide controls lacking in its operations.[28]

51. Meanwhile, related to its Florida operations, Walgreens, while nominally implementing required controls, sought to avoid "documenting [its] own potential noncompliance" regarding "legitimate indicators of inappropriate prescriptions."

52. Walgreens knew that the DEA was conducting a "crackdown on Florida pharmacies where the market is notorious for illicit prescription painkillers" and that Walgreens's own pharmacies accounted for 53 of the top 100 retail sellers of oxycodone in Florida.[29] Walgreens also knew these pills being sold into the "epicenter[s] of [the] notorious well-documented epidemic of prescription drug abuse[,] . . . were migrating to other states," and that many "prescriptions

[27] *See* WAGFLDEA00001861.
[28] *See* WAGMDL00578350.
[29] *See* WAGMDL00119539.

[were] not for a legitimate medical purpose."[30] In addition, Walgreens received presentations highlighting an Ohio drug ring's trips to Florida to get pills, and significant volumes of opioid prescriptions from Florida doctors for Ohio and Kentucky patients being filled in Ohio.[31]

53. Even so, Walgreens still failed to maintain effective control against diversion, including from its Florida stores. Its misconduct continued even after a local police chief in a Florida town started writing letters to two of its pharmacies, which had been the site of multiple arrests "stemming from the prescriptions they filled" and asked for their help "in 'dealing with the prescription medication epidemic.'" The same police chief also met with Walgreens Loss Prevention officials in February 2011, seeking to bring awareness to the problems.[32] Elevating the concerns, he also "sent identical letters to the Chairman and CEO of Walgreens"; the letters described the "bastion of illegal drug sales" that Walgreens pharmacy parking lots had become and sought "their support and assistance in combating the prescription drug epidemic."

54. In 2013, Walgreens reached a Memorandum of Understanding ("2013 MOA") with the U.S. Department of Justice and the DEA to resolve multiple Orders to Show Cause and Immediate Suspension Orders against it. As part of the agreement, Walgreens "acknowledge[d] that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA . . . and its implementing regulations."[33] The 2013 MOA required Walgreens to, among other things,

[30] *See* Stahmann Dep. Dkt. # 1971-2 at 207; *see also* Exh. 46 – Sean Barnes Dep. (10/22/18) at 127:4-12; 255:7-17.
[31] *See* WAGMDL00441397 at WAGMDL041412 – 419.
[32] WAGMDL00490963 at WAGMDL00387660.
[33] WAGMDL00490963 at WAGMDL00490964.

"maintain a compliance program in an effort to detect and prevent diversion of controlled substances" as required by law.[34]

55. As reported[35] by the United States Attorney For the Southern District of Florida, the settlement resulted in a then-record breaking fine for widespread violations of the law:

> Walgreens (Walgreens), the nation's largest drug store chain, has agreed to pay $80 million in civil penalties, resolving the DEA's administrative actions and the United States Attorney's Office's civil penalty investigation regarding the Walgreens Jupiter Distribution Center and six Walgreens retail (collectively "Registrants") in Florida. The settlement further resolves similar open civil investigations in the District of Colorado, Eastern District of Michigan, and Eastern District of New York, as well as civil investigations by DEA field offices nationwide, pursuant to the Controlled Substances (the Act).
>
> The settlement, the largest in DEA history, resolves allegations that the Registrants committed an unprecedented number of record-keeping and dispensing violations under the Act. According to documents filed in the underlying administrative actions, the Registrants negligently allowed controlled substances listed in Schedules II - V of the Act, such as oxycodone and other prescription pain killers, to be diverted for abuse and illegal black market sales.
>
> …
>
> U.S. Attorney Wifredo A. Ferrer stated, "Prescription drug abuse is a tremendous problem in Florida and throughout the country. Every day, individuals die from prescription drug overdoses. The record-keeping requirements of the Controlled Substances Act and DEA regulations are designed to prevent prescription pain killers, like oxycodone, from ending up on our streets. For this reason, we cannot allow pharmacies to circumvent their regulatory record-keeping and dispensing obligations."
>
> The settlement agreement covers conduct that was the subject of DEA's administrative actions and the U.S. Attorney's Office civil penalty investigation. . . . [T]he six retail pharmacies in Florida that received the suspicious drug shipments from the Jupiter Distribution Center, in turn, filled customer prescriptions that they knew or should have known were not for legitimate medical use. In addition, these retail pharmacies and ***others elsewhere in the United States*** failed to properly identify and mark, as required by DEA regulations, hardcopy controlled substance prescriptions that were outsourced to a "central fill" pharmacy

[34] *Id.* at WAGMDL00490968.

[35] https://www.dea.gov/press-releases/2013/06/11/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under

> for filling. Without Walgreens' retail pharmacies identifying these outsourced prescriptions, DEA could not accurately determine which prescriptions were filled from the retail pharmacies' own drug supplies and which prescriptions were filled by a "central fill." Consequently, DEA could not determine the accuracy of the retail pharmacies' drug records. The DEA's administrative actions demonstrated millions of violations of this type.
>
> In addition to the $80 million civil penalty for the above violations, the settlement revokes the Registrants' ability to distribute or dispense controlled substances listed in Schedules II - V for two years, ending in 2014. As part of the settlement, Walgreens admitted that it failed to uphold its obligations as a DEA registrant regarding the above-described conduct. Furthermore, Walgreens has agreed to create a Department of Pharmaceutical Integrity to ensure regulatory compliance and prevent the diversion of controlled substances. Walgreens has also agreed to enhance its training and compliance programs, and to no longer monetarily or otherwise compensate its pharmacists based on the volume of prescriptions filled.

56. Meanwhile, like CVS, Walgreens employed performance metrics for its pharmacists. One former Walgreens pharmacist described management critiques for "not going fast enough" in dispensing prescriptions and believed "[t]hey'd like you to fill one a minute if you could." She recalled there was even a timer to alert her if she was falling behind, and threats of reduced hours or a move to a different store or location.[36] A March 2013 memo confirms that volume targets included controlled substances as late as 2013 and even after the adopting of the GFD policy. Specifically, the memo states, as the response to an "[a]nticipated question" that "GFD concerns doesn't relieve you from trying to attain the numbers that have been set for you."[37] As part of its settlement with the DEA, however, Walgreens agreed to exclude controlled substances calculation from bonus calculations from 2014 forward.[38]

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[36] *Are Business Tactics at Some Pharmacies Risking Your Health?* (Nov. 8, 2017), https://reachmd.com/news/are-business-tactics-at-some-pharmacies-risking-your-health/1610793/

[37] WAGMDL00302949.

[38] WMT_MDL_000048623 at 12 [DEA Settlement Agreement].

57. Even after development and a relaunch of its GFD policy, Denman Murray, Director of Rx Supply Chain Retail, stated in his deposition that, "traditionally, we've always treated a controlled substance like any other, [a] widget's a widget to the system."[39]

B. Walgreens Failed to Maintain Effective Controls Against Diversion from Its Summit County Pharmacies.

58. Although Walgreens had access to significant information about red flags due to its vertical integration with its stores, Walgreens failed to use available information from indicating red flags in order to more effectively prevent diversion.

59. Through 14 pharmacies in Summit County, Walgreens purchased more than ***52 million*** estimated 10mg equivalent pills in Summit County from 2006 to 2014, the years for which ARCOS data is available. Over the same time frame, Walgreens was responsible for 14% of the 10mg equivalent pills purchased in the County.

60. As a vertically integrated distributor and dispenser of prescription opioids, Walgreens knew or should have known that an excessive volume of pills was being sold into Summit County.

61. The sheer volume of prescription opioids distributed to and dispensed by Walgreens pharmacies in and around Summit County is indicative of potential diversion and required appropriate due diligence.

62. Further, analysis of ARCOS data also reveals that, multiple separate Walgreens locations in the County purchased opioid volumes, measured in dosage units and morphine milligram equivalent ("MME") in the 90th percentile among retail and chain pharmacies for a given year.

[39] *See* D. Murray Deposition, 31:20-22 (Jan. 15, 2019).

63. Discovery will reveal that Walgreens knew or should have known that its pharmacies in Ohio, and the surrounding area, including West Virginia, Michigan, and Kentucky, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; filling prescriptions (g) in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. The National Retail Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

64. Because of its vertically integrated structure, Walgreens has access to complete information regarding red flags of diversion across its pharmacies in and around Summit County, but Walgreens failed to utilize this information to effectively prevent diversion.

65. Indeed, police reports describe a Summit County Walgreens as a "known drug area" and a "high drug transaction area." Officers made multiple drug arrests in this Walgreens parking lot within a matter of weeks.

66. In addition, the Ohio Board of Pharmacy suspended the license of a pharmacist at a Macedonia, Ohio Walgreens in 2015 for stealing oxycodone.

67. Walgreens admits its role in the opioid epidemic, stating it has the "ability – and [] critical responsibility – to fight the opioid crisis" as the "nation's largest pharmacy chain" in a time when "[a]ddiction to prescription painkillers, heroin, and other opioids has surged, with opioid overdoses quadrupling in this decade" and "drug overdose deaths – the majority from prescription and illicit opioids" resulting in "more fatalities than from motor vehicle crashes and gun homicides combined." Walgreens also admits the "opioid crisis" is caused by "misuse, abuse and addiction" that result from the "flow of opioids that fuel the epidemic."

iii. Rite Aid Failed to Maintain Effective Controls Against Diversion and Instead Fueled a Black Market in Summit County.

68. Rite Aid's dispensing policies are described as practices the chain was "implementing" in a 2013 Purdue document, but as less detailed than those of CVS and Walgreens.[40]

69. Meanwhile, through eleven pharmacies in Summit County, Rite Aid purchased more than ***35 million*** estimated 10mg equivalent pills in Summit County from 2006 to 2014, the years for which ARCOS data is available. Over the same time frame, Rite Aid was responsible for 9% of the 10mg equivalent pills purchased in the County.

70. As a vertically integrated distributor and dispenser of prescription opioids, Rite Aid knew or should have known that an excessive volume of pills was being sold into Summit County.

[40] PPLPC039000948064, PPLPC039000948068.

71. The sheer volume of prescription opioids distributed to and dispensed by Rite Aid pharmacies in and around Summit County is indicative of potential diversion and required appropriate due diligence.

72. Further, analysis of ARCOS data also reveals that a Summit County Rite Aid purchased opioid volumes, measured in in dosage units and morphine milligram equivalent ("MME") in the 90th percentile among retail and chain pharmacies every year between 2006 and 2014.

73. Discovery will reveal that Rite Aid knew or should have known that its pharmacies in Ohio, and the surrounding area, including West Virginia, Michigan, and Kentucky, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. The National Retail Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

74. Because of its vertically integrated structure, Rite Aid has access to complete information regarding red flags of diversion across its pharmacies in and around Summit County, but Rite Aid failed to utilize this information to effectively prevent diversion.

75. Evidence of diversion should have been apparent from the conduct of its own employees. A Rite Aid pharmacist in the County was arrested for taking narcotics from the store for another's use. Pharmacists at other Ohio Rite Aids have similarly faced disciplinary action related to possible diversion or wrongful prescription of prescription opioids.

76. As another example, Rite Aid stores dispensed opioids to customers of a notorious, convicted pill mill doctor in the County.

77. Confirming its systemic failures to implement and adhere to adequate controls against diversion, Rite Aid has repeatedly faced enforcement actions. In addition to those listed in the Third Amended Complaint, as recently as January 2019, it paid $177,000 into the Naloxone Fund for the State of Massachusetts to resolve allegations that failed to follow regulations designed to prevent substance use disorder in its dispensing of controlled substances, including opioids. Evidencing the systemic nature of the problem, Rite Aid, as part of the agreement, agreed to improve its dispensing practices.

78. In 2018, Rite Aid also agreed to pay a $300,000 settlement for filling Schedule III controlled substances prescriptions in excess of the maximum dosage units allowed to be dispensed at one time.

79. In 2017, Rite Aid paid $834,200 in civil penalties to resolve allegations by the DEA that Rite Aid pharmacies in Los Angeles dispensed controlled substances in violation of the CSA. The DEA's "investigation revealed the incorrect or invalid registration numbers were used at least

1,298 times as a result of Rite Aid's failure to adequately maintain its internal database."[41] Further evidencing the lack of internal controls, the settlement also "resolve[d] allegations that Rite Aid pharmacies dispensed, on at least 63 occasions, prescriptions for controlled substances written by a practitioner whose DEA registration number had been revoked by the DEA for cause."[42]

iv. Walmart Failed to Maintain Effective Controls Against Diversion from Its Summit County Pharmacies.

80. Walmart, throughout the relevant time period, owned and operated pharmacies throughout the United States, including pharmacies in Summit County.

81. Walmart pharmacies in and around Summit County received distributions of prescriptions from Walmart's distribution centers and from other wholesale distributors, which enabled these pharmacies to have the same orders filled by both Walmart and a third-party distributor.

82. The volume of prescription opioids dispensed by Walmart pharmacies in and around Summit County is indicative of potential diversion and required appropriate due diligence.

83. Through just four pharmacies, Walmart purchased nearly ***4 million*** estimated 10mg equivalent pills, or ***4.8 million*** dosage units, of opioids from 2006 to 2014, the years for which ARCOS data is available.

84. As a vertically integrated distributor and dispenser of prescription opioids, Walmart knew or should have known that it was dispensing an excessive volume of pills into and around Summit County.

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[41] DEA, *Rite Aid Pays $834,200 Settlement for Alleged Controlled Substances Act Violations in Los Angeles* (March 9, 2017), https://www.dea.gov/press-releases/2017/03/09/rite-aid-pays-834200-settlement-alleged-controlled-substances-act

[42] *Id.*

85. Discovery will reveal that Walmart knew or should have known that its pharmacies in Ohio, and the surrounding area, including West Virginia, Michigan, and Kentucky, were: (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. The National Retail Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

86. Walmart had complete access to all prescription opioid distribution data related to Walmart pharmacies in and around Summit County.

87. Walmart had complete access to all prescription opioid dispensing data related to Walmart pharmacies in and around Summit County.

88. Walmart had complete access to information revealing the doctors who prescribed the opioids dispensed in Walmart pharmacies in and around Summit County.

89. Walmart had complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in Walmart pharmacies in and around Summit County.

90. Walmart had complete access to information revealing the opioids prescriptions dispensed by Walmart pharmacies in and around Summit County.

91. Walmart had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by Walmart pharmacies in and around Summit County.

92. Walmart had complete access to information revealing the size and frequency of prescriptions written by specific doctors across Walmart pharmacies in and around Summit County.

93. Yet, Walmart failed to put in place effective policies and procedures for the dispensing of prescription opioids. In 2009, the DEA issued a Show Cause order seeking to revoke the registration of a Walmart pharmacy in California. The order alleged that the pharmacy:

> (1) improperly dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances . . . based on Internet prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice . . . ; and (3) dispensed controlled substances to individuals that [the pharmacy] knew or should have known were diverting the controlled substances.[43]

94. In addition, a 2011 Memorandum of Agreement ("2011 MOA") arising out of the investigation states that the DEA also learned that the same pharmacy was allegedly dispensing controlled substances based on prescriptions that lacked valid DEA numbers and allegedly refilling controlled-substances prescriptions too early.

[43] WMT_MDL_000043490.

95. Upon information and belief the failures described in the 2011 MOA were not limited to California but reflected systemic failures at the corporate level. Indeed, the 2011 MOA, which required Walmart to maintain a "compliance program" states that it is applicable to "all current and future Walmart Pharmacy locations."

v. Giant Eagle Failed to Maintain Effective Controls Against Diversion from its Summit County Pharmacies.

96. Although Giant Eagle had access to significant information about red flags due to its vertical integration with its stores, it failed to use available information from indicating red flags in order to more effectively prevent diversion.

97. HBC representatives have admitted that Giant Eagle pharmacy staff have diverted prescription opioids, amounting to tens of thousands of units.

98. Red flags should also have been apparent given that the State of Ohio Board of Pharmacy found that Giant Eagle Pharmacy #4098, in Chardon, Ohio, "from May 1, 2009 through January 21, 2011, fail[ed] to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs, to wit: the following controlled substances and dangerous drugs were stolen from the pharmacy yet internal control procedures failed to deter or detect the theft.":

Drug	**Strength**	**Shortage**	**Percent of Stock**
hydrocodone with APAP	5/325	1,321	53.92
hydrocodone with APAP	5/500	(-648)	0.65
hydrocodone with APAP	7.5/325	5,237	67.49

hydrocodone with APAP	7.5/500	6,161	72.06
hydrocodone with APAP	7.5/750	30,566	57.67
hydrocodone with APAP	10/325	5,282	75.67
hydrocodone with APAP	10/500	14,586	75.19
hydrocodone with APAP	10/650	5,523	82.07
hydrocodone with APAP	10/660	17,512	82.22
hydrocodone with ibuprofen	7.5/200	1,057	52.33
carisoprodol	350	7,556	27.68
Suboxone	8	553	20.04[44]

The State Board further found that "[t]he drugs were stolen by an inadequately supervised technician who admitted to a Board agent that the drugs were diverted to her addicted husband and also sold to another individual." These figures demonstrate Giant Eagle's knowledge of and failure to prevent diversion.

99. Additional unreported diversion from Giant Eagle pharmacies is evidenced in monthly narcotic audit reports and in the testimony of Giant Eagle Pharmacy District Leader Fred

[44] Table from Ohio Board of Pharmacy, Docket Number D-110714-197: *In the Matter of Giant Eagle Pharmacy #4098*.

Bencivengo, who testified as to several instances in a single narcotic audit report where suspected diversions of opioids should have been but were not reported.

100. The sheer volume of prescription opioids distributed to and dispensed by Giant Eagle pharmacies in and around Summit County is indicative of potential diversion and required appropriate due diligence.

101. Discovery will reveal that Giant Eagle knew or should have known that its pharmacies in Ohio, and the surrounding area, including West Virginia, Michigan, and Kentucky, were (a) filling multiple prescriptions to the same patient using the same doctor; (b) filling multiple prescriptions by the same patient using different doctors; (c) filling prescriptions of unusual size and frequency for the same patient; (d) filling prescriptions of unusual size and frequency from out-of-state patients; (e) filling an unusual or disproportionate number of prescriptions paid for in cash; (f) filling prescriptions paired with other drugs frequently abused with opioids, like benzodiazepines, or prescription "cocktails"; (g) filling prescriptions in volumes, doses, or combinations that suggested that the prescriptions were likely being diverted or were not issued for a legitimate medical purpose; and (h) filling prescriptions for patients and doctors in combinations that were indicative of diversion and abuse. Also, upon information and belief, the volumes of opioids distributed to and dispensed by these pharmacies were disproportionate to non-controlled drugs and other products sold by these pharmacies, and disproportionate to the sales of opioids in similarly sized pharmacy markets. The National Retail Pharmacies had the ability, and the obligation, to look for these red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion.

102. In Summit County, Giant Eagle was responsible for more than ***25 million*** estimated 10mg equivalent pills purchased from 2006 through 2014, the period for which ARCOS data is

available. During that time, its twelve pharmacies accounted for 5.32% of the opioids purchased in the County.

103. Further, analysis of ARCOS data also reveals that, a Giant Eagle pharmacy in the County dispensed opioid volumes, measured in morphine milligram equivalent ("MME") in the 90th percentile for its purchases among retail and chain pharmacies every year between 2006 and 2014.

The County amends its Sixth Claim for Relief (Absolute Public Nuisance) as follows:

SIXTH CLAIM FOR RELIEF

Common Law Absolute Public Nuisance
(Against All Defendants)

104. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein unless inconsistent with the allegations in this Count, and further alleges:

105. Defendants created and maintained a public nuisance which proximately caused injury to Plaintiffs.

106. A public nuisance is an unreasonable interference with a right common to the general public.

107. Defendants have created and maintained a public nuisance by marketing, distributing, dispensing, and selling opioids in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiffs' communities, and Plaintiffs and the residents of Plaintiffs' communities have a common right to be free from such conduct and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

108. The public nuisance is an *absolute* public nuisance because Defendants' nuisance-creating conduct was intentional and unreasonable and/or violated statutes which established specific legal requirements for the protection of others.

109. Defendants have created and maintained an absolute public nuisance through their ongoing conduct of marketing, distributing, dispensing, and selling opioids, which are dangerously addictive drugs, in a manner which caused prescriptions and sales of opioids to skyrocket in Plaintiffs' communities, flooded Plaintiffs' communities with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to Plaintiffs and the residents of Plaintiffs' communities.

110. Defendants know, and have known, that their intentional, unreasonable, and unlawful conduct will cause, and has caused, opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Plaintiffs and Plaintiffs' communities.

111. Defendants' conduct has created an ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of Plaintiffs and Plaintiffs' communities. *See* Restatement (Second) of Torts § 821B.

112. The interference is unreasonable because Defendants' nuisance-creating conduct:

a. Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;

b. At all relevant times was and is proscribed by state and federal laws and regulations; and/or

c. Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

113. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

a. The creation and fostering of an illegal, secondary market for prescription opioids;

b. Easy access to prescription opioids by children and teenagers;

c. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;

d. Infants being born dependent on opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

e. Employers have lost the value of productive and healthy employees; and

f. Increased costs and expenses for Plaintiffs relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

114. Defendants intentionally and unreasonably and/or unlawfully deceptively marketed and pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Plaintiffs' communities, a higher level of fear, discomfort and inconvenience to the residents of Plaintiffs' communities, and direct costs to Plaintiffs and Plaintiffs' communities.

115. Each Defendant is liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to Plaintiffs.

116. A violation of any rule or law controlling the sale and/or distribution of a drug of abuse in Plaintiffs' communities constitutes an absolute public nuisance. *See e.g.* R.C. § 4729.35 ("The violation by a . . . person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse . . . constitute[s] a public nuisance[.]").

117. In the sale distribution, and dispensation of opioids in Ohio and Plaintiffs' communities, Defendants violated federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74, and Ohio law, including, but not limited to, R.C. § 4729.01(F~~), R.C. §§ 4729.51-4729.53,~~ and O.A.C. §§ 4729-9-12, 4729-9-16, 4729-9-28, and 4729-9-05(A).

118. Defendants' unlawful nuisance-creating conduct includes violating federal and Ohio statutes and regulations, including the controlled substances laws, by:

a. Distributing, dispensing, ~~by distributors~~ and selling ~~by manufacturers of~~ opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing, dispensing ~~by distributors~~ and selling ~~by manufacturers of~~ opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders;

g. Distributing, dispensing ~~by distributors~~ and selling ~~by manufacturers of~~ opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills;"

h. Defendants' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

i. Distributing, dispensing ~~by distributors~~ and selling ~~by manufacturers of~~ opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

j. Distributing and dispensing ~~by distributors and selling by manufacturers of~~ opioids without maintaining effective controls against the diversion of opioids;

k. Choosing not to effectively monitor for suspicious orders;

l. Choosing not to investigate suspicious orders;

m. Choosing not to report suspicious orders;

n. Choosing not to stop or suspend shipments of suspicious orders; and

o. Distributing, dispensing, ~~by distributors~~ and selling ~~by manufacturers of~~ opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

119. Defendants intentionally and unreasonably distributed, dispensed, and sold opioids that Defendants knew would be diverted into the illegal, secondary market and would be obtained by persons with criminal purposes.

120. The Marketing Defendants intentionally and unreasonably engaged in a deceptive marketing scheme that was designed to, and successfully did, change the perception of opioids and cause their prescribing and sales to skyrocket in Plaintiffs' communities.

121. The Marketing Defendants intentionally and unreasonably misled Plaintiffs, healthcare providers, and the public about the risks and benefits of opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

122. The Marketing Defendants violated Ohio and federal statutes and regulations, including the controlled substances laws, by engaging in the deceptive marketing of opioids, as described in this Complaint.

123. In the distribution, dispensation, and sale of opioids in Ohio and Plaintiffs' communities, Defendants violated and/or aided and abetted violations of R.C. § 2925.02(A), which states:

> "No person shall knowingly do any of the following:
>
> (1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance; . . . or
>
> (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent."

124. ~~Defendants are in the business of manufacturing, marketing, selling and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.~~ Defendants are in the business of manufacturing, marketing, distributing, and/or dispensing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

125. Indeed, opioids are akin to medical-grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to Plaintiffs—exactly as would be expected when medical-grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

126. Defendants had control over their conduct in Plaintiffs' communities and that conduct has had an adverse effect on rights common to the general public. Marketing Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems they developed to prevent diversion, whether they filled orders they knew or should have known were likely to be diverted or fuel an illegal market.

127. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to Plaintiffs described herein.

128. Because of the Marketing Defendants' deceptive marketing of opioids and Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

129. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Plaintiffs' communities and the harm inflicted outweighs any offsetting benefit.

130. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

131. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiffs have suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

132. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, Plaintiffs have suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

133. The nuisance created by Defendants' conduct is abatable.

134. Defendants' misconduct alleged in this case is ongoing and persistent.

135. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. Plaintiffs allege wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

136. Plaintiffs have incurred expenditures for special programs over and above Plaintiffs' ordinary public services.

137. Plaintiffs seek to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

138. Plaintiffs have suffered, and will continue to suffer, unique harms as described in this Complaint, which are of a different kind and degree than Ohio citizens at large. These are harms that can only be suffered by Plaintiffs.

139. Plaintiffs are asserting their own rights and interests and Plaintiffs' claims are not based upon or derivative of the rights of others.

140. The tortious conduct of each Defendant was a substantial factor in creating the absolute public nuisance.

141. The tortious conduct of each Defendant was a substantial factor in producing harm to Plaintiffs.

142. Plaintiffs have suffered an indivisible injury as a result of the tortious conduct of Defendants.

143. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

144. Plaintiffs assert this Cause of Action as a common law tort claim for absolute public nuisance and not as a "product liability claim" as defined in R.C. § 2307.71. In this Count, Plaintiffs do not seek damages for death, physical injury to person, emotional distress, or physical damages to property, as defined under the Ohio Product Liability Act.

145. Plaintiffs seek all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre and post-judgment interest.

Respectfully submitted,

Dated: November 20, 2019

/s/ Linda Singer

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 20th day of November, 2019, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF Systems.

/s/ Linda Singer
Linda Singer
Attorney for the Plaintiffs